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(54) Abstract Title
Surgical simulators

(57) A surgical simulator includes a simulated torso having an abdominal cavity within which a simulated aorta (4) is located. An opening in the torso provides access to the abdominal cavity and interchangeable, removable plates are provided for closing the access opening. The torso is formed with groin crease cut-outs (1) which incorporate pre-cut access cavities to facilitate the entry of endovascular stent graft instrumentation. A sensor system is provided for monitoring the carrying out of simulated surgical techniques. The sensor system comprises a digital camera (14) movable along a track fixed to a plate removably mounted in an access opening of the abdominal cavity of the torso.

Figure 1

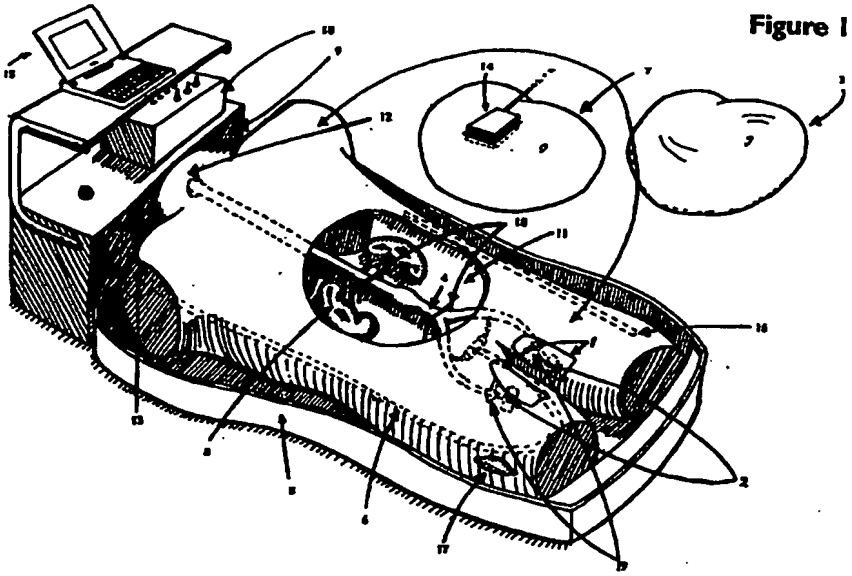

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Figure I

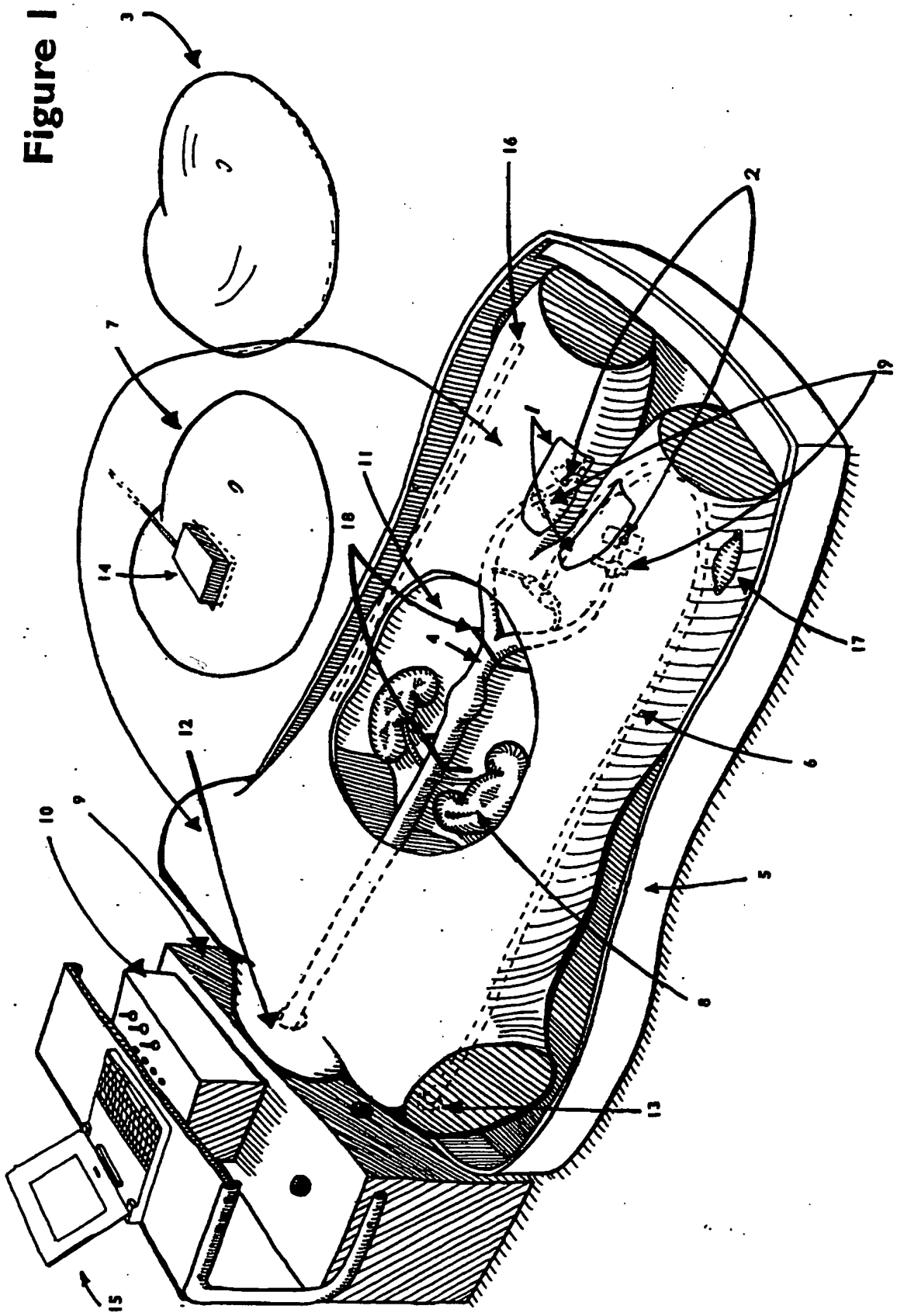


Figure 2

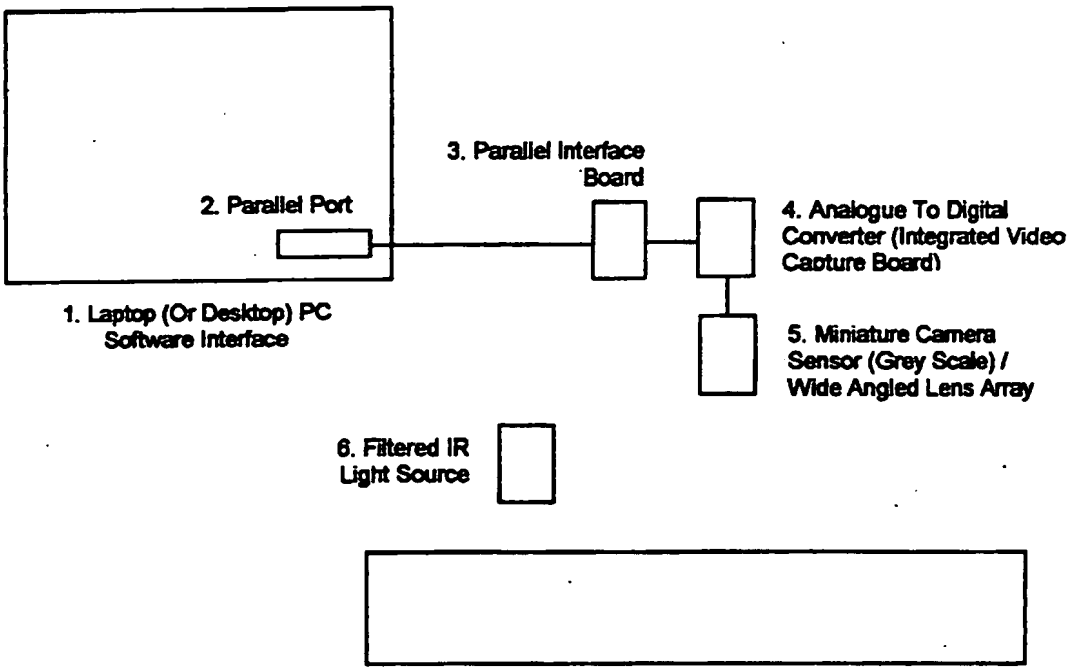

3. Parallel Interface Board
2. Parallel Port
4. Analogue To Digital Converter (Integrated Video Capture Board)
1. Laptop (Or Desktop) PC Software Interface
5. Miniature Camera Sensor (Grey Scale) / Wide Angled Lens Array
6. Filtered IR Light Source
7. Simulated Abdominal Aortic Aneurysm Assembly

FIG. 3

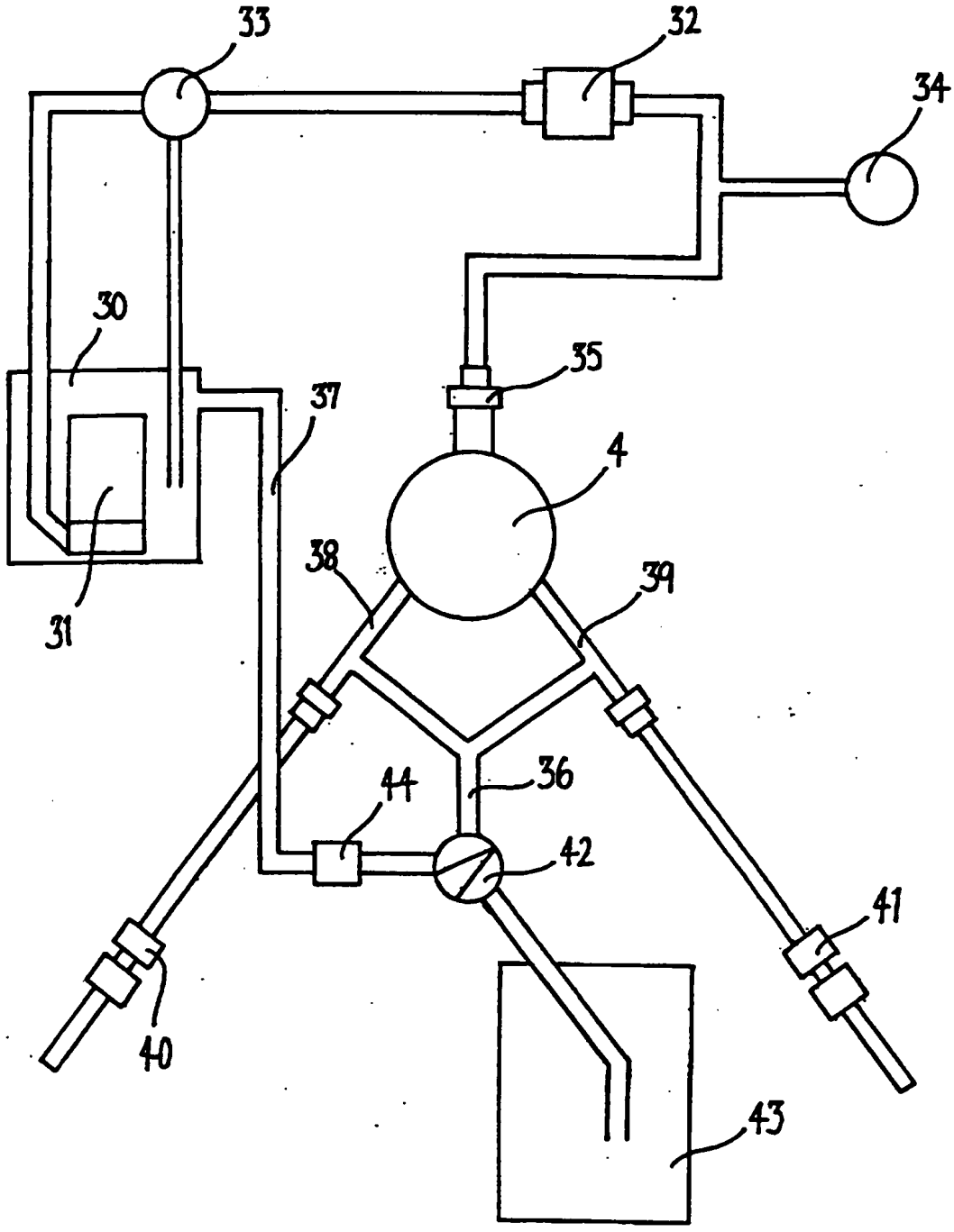
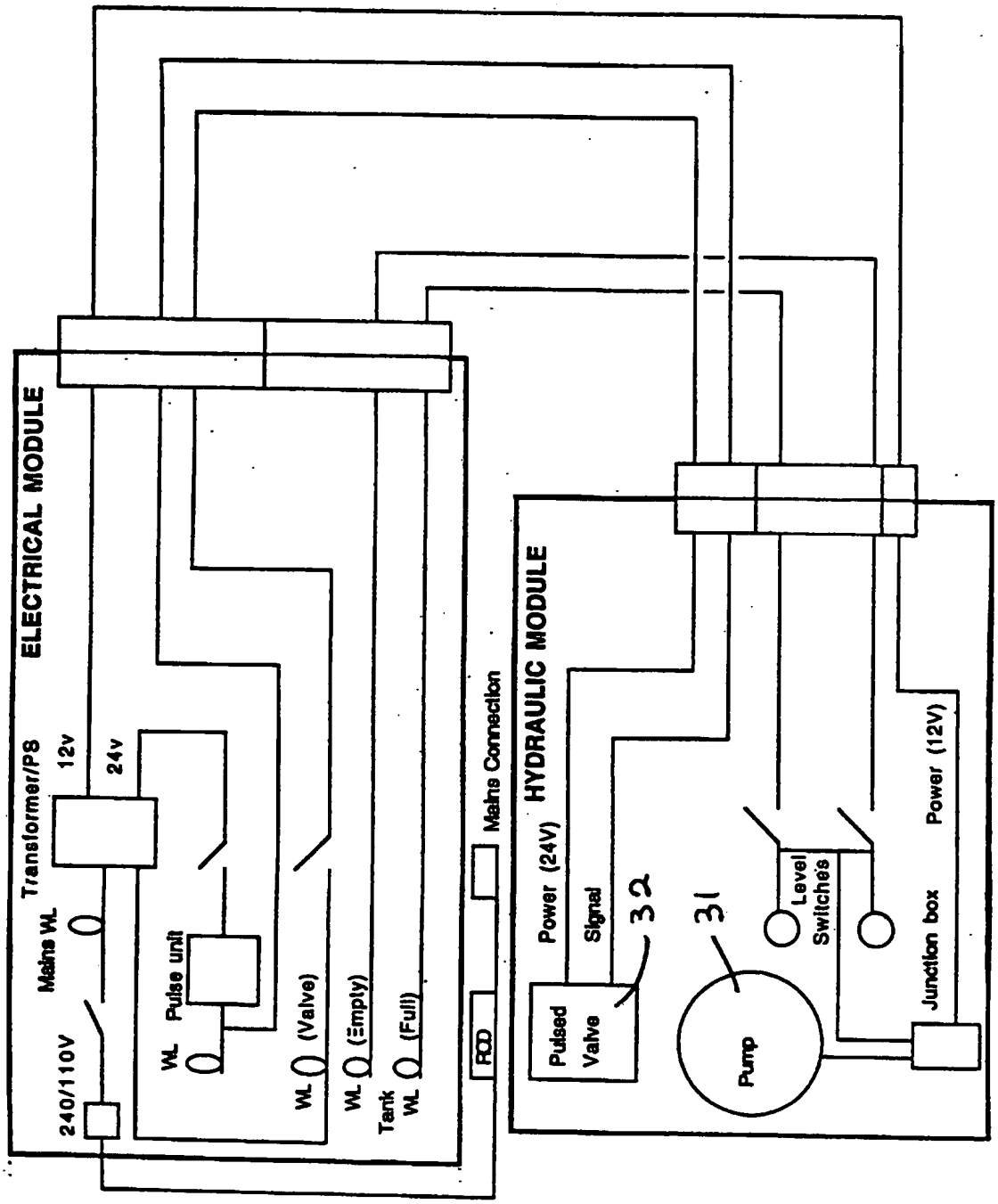


Figure 4


ELECTRICAL MODULE
Transformer/PS
12v
24v
Mains WL
240/110V
WL
Pulse unit
WL (Valve)
WL (Empty)
Tank
WL (Full)
ROD
Mains Connection
HYDRAULIC MODULE
Power (24V)
Signal
32
Pulsed Valve
31
Pump
Level Switches
Junction box
Power (12V)

SURGICAL SIMULATORS

Field of the Invention

This invention relates to surgical simulators and one aspect thereof concerns a method of constructing a simulation system for use by vascular surgeons and interventional radiologists when carrying out endovascular surgical techniques within the principal arterial system of the human body namely the aorta and femoral arteries.

Major degenerative arterial disease processes of the central human vascular system affect up to ten percent of the human adult population, particularly males, in the seventh and eighth decades of life. One such disease process, known as aneurysmal pathology, causes major structural weakness in the wall of the human thoracic aorta, abdominal aorta, and iliac arteries. Such aneurysms typically lead to ballooning (either localised or diffuse) of the affected arterial wall, which is associated with a significant risk of mortality if not rapidly treated.

Modern methods of diagnosis, and increased standards of health awareness in the general population as a whole have lead to an ever-increasing number of corrective surgical interventions being undertaken for the treatment of aneurysms.

Traditionally, surgical treatment of aneurysms located in the human aorta has involved creating surgical access to the pathology by means of a large midline abdominal incision. The trauma of creating the requisite surgical exposure is in itself associated with a high degree of morbidity and mortality. Many patients are elderly, debilitated, and pose a major (often unacceptable) surgical and anaesthetic risk.

Major advances in surgical techniques over the last three years have made it possible to treat abdominal aortic aneurysms by means of a minimal, endovascular approach. In essence, it is now feasible to introduce a stent graft into the diseased portion of the human aorta through access incisions created in the femoral artery(ies), at the groin.

Because of the nature of the minimally invasive procedure, it can be undertaken with the assistance of diagnostic fluoroscopy at key stages of the procedure itself. The techniques associated with introducing, and successfully deploying the stent graft systems, are complex and there is an inherent 'learning curve' in mastering them.

The procedures are typically undertaken by vascular surgeons and/or interventional radiologists. The need to undertake adequate training in the deployment of stent grafts prior to in-vivo treatment of human patients is widely recognised. Methods of undertaking such training have included the use of in-vivo animal models, but because of major anatomical (and pathological) differences between such animal models and the human, in

addition to increasing political and moral objections to such practice, the need to develop a practical and fully portable functionality simulator to train surgeons and interventional radiologists in endovascular surgical techniques has become essential.

It is accordingly an object of the present invention to provide an improved method of making such a simulator, and a simulator made by such method.

SUMMARY OF THE INVENTION

According to a first aspect of the present invention, there is provided a method of making a surgical simulator which includes:-

a) producing a simulated torso having an abdominal cavity within which a simulated aorta is located, the torso having an opening which permits access to the abdominal cavity, and

b) providing a plurality of interchangeable removable plates for closing said opening, the plates having different characteristics and permitting the practising of different surgical procedures, and

c) the simulated torso being so formed as to permit the insertion of a stent graft into the simulated aorta.

According to a second aspect of the present invention there is provided a surgical simulator produced by the above method.

According to a third aspect of the present invention there is provided a method of training surgeons and/or radiologists which

includes the use of a surgical simulator produced by the method defined above.

When carrying out said method of training, a sensor system is preferably employed, the sensor system comprising a digital camera movable along a track fixed to a plate removably mounted in the access opening of the abdominal cavity.

According to a further aspect of the present invention there is provided a sensor system for monitoring the carrying out of simulated surgical techniques, said sensor system comprising a digital camera movable along a track fixed to a plate removably mounted in an access opening of an abdominal cavity of a simulated torso.

The simulator of the present invention is fully integrated, self-contained, and totally portable, suitable for use in any potential training environment.

The simulator is anatomically accurate, replicating the essential relevant external and internal soft tissue and hard tissue bodily landmarks.

The simulator is capable of providing the full range of training experience modalities for rehearsing endovascular surgical techniques, namely:-

1) Introduction and deployment of endovascular stent grafts under direct vision, facilitated by incorporating a

removable/replaceable transparent moulded aperture located at the abdominal region of the simulated torso.

2) Introduction/deployment of endovascular stent grafts using conventional fluoroscopic imaging equipment. The simulated, anatomically-accurate torso, is constructed from materials in morphologically-accurate form, such that the simulator displays visually the key landmarks of the bony skeleton, when viewed by means of a fluoroscope.

3) Introduction and deployment of endovascular stent grafts utilising a digital miniature monochrome (or colour) infra red-sensing camera sensor system located within an opaque silicone-covered removable/replaceable aperture plate within the abdominal region of the simulated torso. This system is designed to replace the need to use fluoroscopic imaging equipment, in those circumstances where such equipment is unavailable, but affording the clinician a realistic means for rehearsing the deployment of endovascular device without direct vision.

The simulator provides a self-contained, integrated, and variable circulating fluid pumping system capable of accurately simulating the physiological flow characteristics within the human aorta, iliac and femoral arteries.

The simulator incorporates interchangeable simulated aneurysmal aortic models of variable morphologies and degrees of complexity.

The modular design of the simulation system provides for use of the simulator with a full range of endovascular surgical techniques, both existing and those currently under development.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of the fully anatomical simulated torso, showing the relationship and structure of the principal components of the simulation system,

Figure 2 shows the flow diagram and circuitry describing the simulator computer-controlled miniature digital infra-red-sensing camera sensor system,

Figure 3 shows the flow diagram describing the hydraulic circuit for the simulator circulating fluid pumping system, and

Figure 4 shows the flow diagram describing the electronic control circuitry for the circulating fluid pumping system.

Description of the Preferred Embodiments

The simulator comprises the following features:-

1. A simulated fully anatomical human torso replicating the area from the neck to the upper thighs, incorporating appropriate abdominal and groin access cut-outs.
2. A computer-controlled, miniature infra red camera sensor system, designed to replace the need to use fluoroscopic

imaging equipment, where such equipment is unavailable. A dedicated laptop PC/software image manipulation can be supplied with the simulated system.

3. A mains-powered, multi-voltage compatible pumping system designed to simulate the physiology of aortic blood flow characteristics.
4. Transparent simulated aortas, incorporating variable aneurysmal morphologies, all of which are fully interchangeable.

A fully anatomical simulated human torso is shown in Figure 1. The torso is constructed principally from two components, the first (uppermost) being a fully-anatomical jacket manufactured from silicone rubber polymers and the second (lowest) manufactured from glass-reinforced polyester. The simulated torso is manufactured from moulds created from an in-vivo body casting of the anterior torso of a male subject, utilising an alginate (hydrocolloid) impression medium. A series of positive and negative moulds are created from the anatomical casting. A positive glass-reinforced polyester forming is manufactured to incorporate a series of locating keys across its entire anterior surface. Separate moulds are utilised to manufacture the silicone rubber jacket. When fully polymerised, the 10 mm. thick silicone jacket is affixed permanently to the polyester torso base utilising a transparent silicone adhesive (Elastosil E43, Wacker Industries GmbH).

It should at this stage be noted that appropriate anatomical cut-outs are created in the master moulding of the silicone jacket to facilitate the appropriate surgical access points for the simulation of

the surgical procedure. One cut-out is located at the abdominal aspect 7 of the moulding. Two further cut-outs are created within the medial aspect of both simulated groins 1.

The abdominal cut-out is cast from a separate mould, created from the original master torso moulding. The abdominal cut-out silicone jacket is fixed by means of a transparent silicone adhesive (Elastosil E43 Wacker Industries GmbH) to a 3mm-thick, high-impact polystyrene plate created from an acrylic resin mould of the abdominal cut-out, by means of a vacuum forming process.

Three types of removable abdominal cut-out plate are provided for use with the simulator:-

(i) the first comprises a silicone jacket permanently located to a solid vacuum-formed sub-plate. This cut-out is provided with a miniature digital, infrared-sensing board camera sensor unit 14 movable along a track permanently affixed to the sub-plate undersurface, through which protrudes a wide-angle camera lens unit. The camera sensor is hard-wired to a dedicated laptop (or desktop) PC 15 located on a stainless steel platform at the head of the simulator torso.

(ii) the second comprises a silicone jacket permanently located to a vacuum-formed sub-plate which has an ovoid cut-out 3. The size of the ovoid cut-out is determined by the necessity to create an accurate appearance on the fluoroscope screen (when the simulator is being used with such equipment). This is achieved by undertaking a series of validation tests with fluoroscopic imaging equipment, whereby all of the materials from which the simulator unit is constructed are evaluated to determine their

relative radiopacities and radiolucencies. In this way, it is possible to accurately recreate the fluoroscopic appearance of the relevant internal anatomical structures of the simulated torso. (This particular plate is designed specifically for use with fluoroscopic equipment.).

The first and second plates are each provided with two nylon looped tabs (permanently fixed to the sub-plates) to facilitate rapid removal/replacement of the abdominal cut-out plates, and to minimise trauma to the silicone rubber jacket during removal/replacement.

(iii) the third comprises a totally transparent plate designed to push-fit into the abdominal cut-out recessed within the silicone rubber jacket 3. The plate is fabricated from 3 mm. thick transparent polyethylene G (PETG) by means of a vacuum-forming process. This plate allows the direct visualisation of the internal structure of the simulator, thus allowing the deployment of an endovascular stent graft, under "direct vision".

All three plates are fully interchangeable within the recessed silicone rubber jacket abdominal cut-out. The height and fit of the plates with the abdominal cut-out can be adjusted by means of four natural nylon 66 pan-head M6 threaded screws located to the polyester torso by means of four translucent polycarbonate locating lugs. It should be noted that the silicone rubber torso jacket and abdominal cut-out jackets are coloured to replicate the appearance of human skin, and are formulated to replicate the equivalent Shore Hardness of human skin.

The two groin crease cut-outs 1 each incorporate a pre-cut elliptical access cavity, to facilitate the entry of appropriate endovascular stent graft instrumentation. The cut-outs 1 are closed by pads which are removable/replaceable, are constructed from the same silicone rubber as the surrounding torso jacket, and are affixed to styrene locating struts within the polyester base groin cut-outs by means of integral natural nylon 66 push-fit clips.

The entire simulated torso is located to a glass fibre reinforced moulded polyester base plinth 5. The torso is affixed to the base plinth 5 by means of a natural nylon 66 hinge (with a stainless steel hinge pin) located at the simulated torso neck.

The entire torso assembly can be lifted upwards by means of polypropylene D-handles 17 fixed to the lateral aspects of both simulated thighs. The torso can be supported in its maximum lifted position by means of an extruded glass reinforced polyester supporting rod 16 which is permanently hinged to the torso base plinth 5 by means of a fabricated aluminium hinge block, and which locates into a recess within the underside of the polyester torso base at the left thigh. The supporting rod 16 is radiolucent when viewed through fluoroscopic imaging equipment, therefore not detracting from the images produced. The rod 16 is covered with black heat-shrink PVC sleeving to eliminate reflective glare when viewed with the digital camera sensor unit 14.

The polyester torso-supporting plinth 5 is shaped to follow the outline of the torso itself, and incorporates an anatomically-sculpted

platform which simulates the lower lumbar, sacral, and coccygeal aspects of the vertebral column (with intervertebral spaces), pelvic floor, ischial prominences, and the upper aspect of the left and right femurs. The moulding is designed to accurately simulate the fluoroscopic appearance of the bony anatomical landmarks described, to allow the simulator operator to accurately orientate the placement of endovascular stent grafts within the aneurysmal section of the aorta. A 35 mm. wide margin surrounding the raised platform is treated with matt black paint to reduce reflective glare from the natural white simulator plinth when viewed with the camera sensor 14.

The anatomical platform integrated with the base plinth 5 is in turn covered with a removable, magenta-red, 6 mm. thick, moulded silicone cushion 11. The cushion 11 is coloured accurately, to reproduce the appropriate appearance on the laptop computer screen linked to the miniature infra-red camera sensor. The cushion 11 is contoured accurately to support the simulated model of the aneurysmal aorta, iliac arteries, and femoral arteries. A series of silicone cushions are available to correspond accurately with the external morphology of different aneurysmal aorta models, all of which fit accurately to the polyester anatomical platform. The silicone cushions are also designed to accurately simulate the tactile feedback of the bony landmarks associated with the passage of endovascular instrumentation.

Simulated silicone kidneys 8 are placed onto the silicone cushion 11 at the correct anatomical position beside the aneurysm model and incorporate radiopaque simulated infra-red renal arteries

ensuring realistic appearance when viewed by the camera sensor or fluoroscope.

Interchangeable models of the aneurysmal aorta 4 are provided for use with the simulator. The aneurysm models comprise the aortic neck proximal to the aneurysm, the aneurysm sac, aorta distal to the aneurysm, common iliac arteries, internal and external iliac arteries, and upper aspect of the femoral arteries. The transparent models of the aneurysmal aorta are provided by Baxter Healthcare Corporation, Vascular Systems Division. The simulator is designed to accept multiple morphological variants of aneurysmal pathology, thereby providing training in treating pathologies of varying degrees of difficulty.

The entire aneurysmal aorta simulation is connected to a closed-circuit flow system within the simulated torso, and is in turn connected to the flow circuit system of Figure 3, as described below.

The inflow aspect of the circuit commences at the simulated torso neck 12 by means of a permanent 19 mm. bore quick-fit coupling incorporating a non-return valve (RS Components Ltd UK). The coupling is connected to a silastic tube (19 mm. bore, 2.5mm wall, SAMCO LTD UK) by means of a black nylon 66 double tang clip (Heyco Ltd, UK). The distal end of the tube is connected to the proximal neck of the aneurysmal aorta model by means of a 19 mm. bore quick-fit coupling with non-return valve (RS Components UK) and black nylon 66 double tang clip (Heyco Ltd UK).

The outflow section of the circuit commences at the common junction of the simulated left and right internal iliac arteries, which is connected proximally to a 6 mm. bore quick-fit coupling with non-return valve (RS Components UK) and black nylon 66 double-tang clip (Heyco Ltd UK). The distal connection is made through the same coupling to a 10 mm. bore 2 mm. wall thickness silastic tube (Samco Ltd UK) which leaves the simulated torso at the right shoulder 13 by means of a permanently-fixed 13 mm. quick-fit coupling with non-return valve (RS Components UK).

Access for endovascular instruments via the two groin entry points is facilitated by means of assemblies connected to the two external iliac arteries. The assemblies include simulated femoral arteries consisting of 8 mm. bore, 2 mm. wall thickness silastic tubing (Samco Ltd, UK) connected to barbed stainless steel adaptors (8 mm. diameter bore, 1.0 mm. wall thickness) which push-fit into the distal ends of the simulated external iliac arteries, within the aneurysmal aorta model, both ends being secured with black nylon 66 double tang clips, (Heyco Ltd, UK).

The simulated femoral arteries are fixed to the polyester torso base by means of black nylon 66 double tang clips (Heyco Ltd, UK). The distal ends of the simulated femoral arteries are connected to polycarbonate surgical trocar reducers 2 (Richard Allen Surgical, USA) which incorporate a diaphragm valve, by means of grey PVC tapered push-fit adaptors.

Pinch valves 19 are placed over the two simulated femoral artery tubes, to prevent loss of circulating fluid, prior to the

introduction of endovascular instrumentation. The pinch valves comprise specially modified Zachary-Cope intestinal clamp inserts with a customised quick-release latch. The non-return valves within the surgical trocar reducers 2 prevent fluid loss as soon as the endovascular instrumentation has been introduced through them, and the pinch valves released.

The surgical trocar reducer/femoral artery assemblies can be replaced as and when necessary. The entire aneurysmal aorta model assembly can be rapidly removed from the flow circuit inflow and outflow by means of the quick-fit couplings. The non-return valve in the couplings prevent significant fluid loss during the changeover process. Rapid changeover of the aorta assemblies allows for continuous use of the simulator between successive operators, and allows the retrieval/recycling of expensive deployed stent graft devices.

Similarly, interchangeable aneurysmal aorta models of different morphology(ies) (and their corresponding silicone supporting cushions) can be easily and rapidly fixed to the polyester torso base.

Radiopaque stainless steel marker pins 18 are placed into the AAA model silicone cushion 11 at the level of the infrarenal arteries and at the bifurcation of the common iliac arteries. The markers are covered with black PVC heat shrink sleeving, to optimise their appearance when viewed by either fluoroscopy or by the digital camera sensor system.

A COMPUTER-CONTROLLED MINIATURISED INFRA RED SENSING DIGITAL BOARD CAMERA SENSOR SYSTEM AND SOFTWARE DESIGNED TO REPLACE THE NEED TO USE FLUOROSCOPIC IMAGING EQUIPMENT.

One of the principal innovations developed for this simulation system is the design and implementation of a fully-portable, compact, and self-contained sensor system, which is provided for the purpose of replacing the need to use fluoroscopic imaging (where such imaging equipment is not available).

The sensor system comprises a miniaturised, infra-red sensing, monochrome digital board camera 14 (16-shade grey scale, 320 x 240 pixels (CONNECTIX, QUICK CAM 100, USA)) located within a hermetically-sealed polypropylene enclosure, permanently fixed to the removable abdominal cut-out plate (See Figure 1).

The board camera 14 is focused by means of a customised wide angle lens optic with a field of view of 108 degrees (LENS V4301 Marshall Optical Systems, USA). The focal distance between the lens unit and the object is 10 cms. The camera is able to view the simulated abdominal aortic aneurysm model from proximal aortic neck to internal and external iliac arteries (a focal field of approximately 30 cms. long by 20 cms. wide).

The camera/lens unit is connected to the parallel port of a standard IBM personal computer (capable of operating on, Microsoft Windows 98, Microsoft Windows 95 or Microsoft

Windows 3.11). The signals transmitted by the camera/lens unit are relayed to the PC via an analogue to digital converter (an integrated video capture board) and then through a parallel interface board.

A functional diagram describing the system sequencing is shown in Figure 2.

The sequencing of events occurring with the sensing system are as follows:

1. Digital Camera Image Update - Image Capture (15 frames/second).

2. Image output via parallel interface to PC parallel port.

3. Software frame grabbing from parallel port input.

4. Software manipulation (image formatting/sizing).

5. Screen image update.

Thus, the images relayed by the camera 14 of the endovascular surgical procedure are processed and manipulated by a customised software program as described in a functional specification supplied by Simutech Limited and written and designed by JFH Medical Limited, UK.

Essentially, the camera sensor system is able to display the real-time introduction and deployment of endovascular stent graft devices in a manner which obviates the need to use conventional fluoroscopic imaging equipment.

The coloration of the soft silicone cushion 11 surrounding the simulated aortic aneurysm model, and the simulated silicone kidneys/renal arteries ensure that the image displayed on the P.C. screen closely resembles that of a conventional fluoroscopic image.

One of the key procedures when undertaking endovascular surgical techniques is that of taking real time fluoroscopic images at the vital stages in introducing and deploying the stent graft. This is achieved through the use of an X-ray contrast medium, a radiopaque marker solution introduced into the proximal aorta. The simulator flow circuit is designed to be compatible with typical contrast media (such a UROGRAFIN 370, Schering Healthcare UK). Importantly, however, the camera sensor system is designed to be able to recreate the effects of injecting a bolus of contrast medium. To achieve this, a series of contrast medium analogue solutions was designed such that their respective colour balances are optimally detected by the camera sensor system. The solutions developed are optically-dense suspensions, which are introduced in 5 millilitre boluses through an inlet port fabricated into the flow circuit inlet tube, located at the torso neck. Typically four 5 millilitre boluses are introduced during the course of an endovascular procedure. The flow circuit can be rapidly diverted following the introduction of the contrast medium analogue dye, to ensure that the circulating fluid returns to its 'normal' clear appearance. The

typical dwell time from contrast medium injection to imaging on the PC screen is approximately 10 seconds during the simulated procedure, and the circuit is placed on 'divert' for a further 10 second period to ensure that the circulating solution then returns to optical clarity.

The formulation of the contrast medium analogues developed for use with the simulator include: PHOSPHATE BUFFERED BASE ZINC SALT IN DEIONISED AQUEOUS SUSPENSION. These media are supplied in 100 millilitre quantities with the simulator.

The software program is designed to display the realtime deployment of endovascular devices on the PC screen in a manner which simulates the appearance of a fluoroscopic image. It is also possible to simultaneously display stored angioscopic images of simulated endovascular procedures on the PC screen, facilitating a direct correlation between the fluoroscopic appearance and the camera sensor appearance during the key stages of stent graft development. It is also possible for the simulator operator to store the entire simulated procedure on the laptop/desktop for storage and /or replaying at a later time, or to frame - grab individual images from the procedure for storage and/or replay at a later time.

Dimensional calibration of the software system with the particular aortic aneurysm model in use at any one time within the simulator is achieved through the use of two stainless steel marker pins 18 which push-fit (infinitely adjustable) into the aneurysm model silicone supporting cushion 11 located at the level of the

infra renal arteries and at the point of bifurcation of the common iliac arteries 18, Figure 1. The actual distance between the marker pins 18 is measured (in centimetres) and the co-ordinates entered into the software, which then calibrates the system, displaying a scale (marked in millimetres) alongside the image of the simulated aortic aneurysm model created by the camera sensor. This procedure replicates that utilised clinically during the use of fluoroscopy, and the radiopaque markers pins 18 supplied with the simulator also serve the needs of undertaking procedures on the simulator in association with fluoroscopic equipment. It is also possible for the software to provide anatomical reference parameters by manipulating stored images (image processing).

Other interactive software features of the system are:

(i) The ability to provide overlaid footage of clinical endovascular procedures, displaying the key features of deployment of specific endovascular devices (timed to coincide with the realtime images of the simulated procedure).

(ii)The ability to introduce previously stored surgical 'complications', which can be randomly introduced by the simulator operator by means of the PC keyboard. An interactive question and answer format requires that the surgical/radiological trainee responds in the correct manner before proceeding with the surgical simulation. Responses can be recorded for playback at the end of the training session, and time(s) to respond can be recorded also.

The camera sensor is designed to operate in low light conditions, but in those situations where the simulator is to be used

in a completely darkened operating room, a tungsten/halogen/infra-red light source of appropriate wavelength is provided with the simulator.

The operation of the simulator under very low light conditions can be optimised through the use of an appropriate miniature digital colour board camera sensor in conjunction with appropriate coloured filter shields placed over the camera optics.

In summary, the innovative features and advantages of the camera sensor/interface/software system described above are as follows:

(i) The camera system is capable of being fixed permanently to the simulator and does not require to be moved to obtain the required visual field (provided by dedicated wide angle lens optics).

(ii) The camera system is digital and can either be monochrome (16 shades greyscale, 320 x 240 pixels) or colour (used in conjunction with appropriate lens filter elements).

(iii) The camera sensor utilises 'plug and play' technology, i.e. it is external to the PC, via the PC parallel port. Camera power is derived from the PC keyboard.

(iv) The system is fully portable, in that it does not require any hardware modification to the operating PC and is compatible with any IBM PC operating on Microsoft Windows 95, 98 or 3.11.

(v) The camera is fully controlled by the PC and does not require any external drives, boards, or displays.

(vi) Software operation (video captive etc) is by means of the PC keyboard or mouse.

(vii) It is possible to eliminate the need to use the keyboard at all by using a keyboard emulator.

(viii) Requisite anatomical reference points for the simulated endovascular procedure is provided by means of the software (i.e. by image processing).

(ix) Camera sensor images are continuously displayed (up to 15 frames per second) on the PC simulator and video capture can either be continuous or single frame. Image capture is initiated by means of the keyboard or mouse, and is only active if a permanent record is required by the operator.

(x) Simulated aortograms (fluoroscopic images) are produced as required, by means of the keyboard, and can either be simultaneously displayed alongside the realtime images created by the camera sensor , or can be displayed as image overlays.

3. A mains-powered, multi-voltage compatible circulating fluid pumping system designed to accurately replicate the physiology of the flow characteristics of the human aorta.

As shown in Figure 3, the device provides a supply of fluid to an artificial aorta 4 (which has an aneurysm) to simulate the flow of blood through the aorta and local arteries. The system operates using using a fluid holding reservoir 30 containing a submerged centrifugal pump 31 which provides a controlled supply of fluid to a pulsed electrically operated solenoid valve 32. The line between the pump 31 and the pulsed valve 32 includes a pressure-regulating valve 33 and the pressure of fluid supplied to the aorta is indicated by means of a pressure gauge 34.

The circulating fluid preferably comprises a Phosphate-buffered 0.9% saline solution, incorporating Bronopol as a preservative. The outlet from the solenoid valve 32 is connected via flexible hosing and quick release sealing connectors 35 to the aorta inlet. The pressure gauge 34 shows the solenoid valve outlet pressure. The aorta 4 has three outlets, the main outlet 36 is connected to return the fluid back to the reservoir 30 via flexible hosing 37, the secondary outlets 38 and 39 are normally shut off with valves 40 and 41 and provide access to the aneurysm to carry out endovascular procedures. The returning fluid passes through a diverter valve 42 which normally returns the fluid to the reservoir 30 but can be used to drain off fluid to an external vessel 43 when required. An optional check valve 44 is located between the diverter valve 42 and the reservoir 30.

The system operates with 110/240V AC supplies and is fully protected using a Residual Current Detector (RCD) as well as being fully earthed. The system utilises a control box containing the necessary electrical and electronic control systems and a hydraulics box containing the fluid reservoir and hydraulic components. All electrical components contained in the hydraulics box are low voltage (12/24) and are designed to work in a hydraulic system. A control lead is used to connect the control box to the hydraulics' box. Figure 4 shows the circuit diagram of the electrical control system.

The control box contains a power supply unit which can automatically operate on either a 110 or 240V AC supply. An

ON/OFF switch and warning light are provided to control the mains supply. The power supply unit provides both 12V and 24V DC for use with the pump 31 and the solenoid valve 32. The pump 31 is controlled with an ON/OFF switch on the control box and has a warning light which shows when the pump is running. The solenoid valve 32 is supplied with a 24V pulsed signal controlled by a timer unit normally following the introduction of a contrast medium/analogue. The timer unit is programmed to provide both the pulsing rate and the pulse duration for the fluid pulsing characteristics. These parameters may be adjusted to provide the desired pulsing rate, duration, flow rates, and maximum/minimum operating pressures. A warning light is also used to visualise the pulse supply.

The entire system is designed to simulate the typical physiological flow and pressure values present in the human aorta/iliac arteries/femoral arteries.

Certain types of endovascular stent grafts are constructed from 'shape memory' alloys, such as "Nitinol". These devices rely on the graft reaching normal body temperature during deployment to expand, and to therefore locate to the arterial wall. Whilst the current flow circuit does not require it, the circuit preferably incorporates an appropriate thermostatically-controlled heating element within the holding reservoir tank, as required.

Claims:-

1. A method of making a surgical simulator which includes:-

a) producing a simulated torso having an abdominal cavity within which a simulated aorta is located, the torso having an opening which permits access to the abdominal cavity, and

b) providing a plurality of interchangeable removable plates for closing said opening, the plates having different characteristics and permitting the practising of different surgical procedures, and

c) the simulated torso being so formed as to permit the insertion of a stent graft into the simulated aorta.

2. A method as claimed in Claim 1, which includes providing a sensor system for monitoring the carrying out of the simulated surgical techniques.

3. A method as claimed in either of the preceding claims, which includes providing the simulated torso with groin crease cut-outs.

4. A method as claimed in Claim 3, in which each of the groin crease cut-outs incorporates a pre-cut elliptical access cavity to facilitate the entry of endovascular stent graft instrumentation.

5. A method as claimed in any one of the preceding claims, which includes mounting the simulated torso on a torso-supporting plinth which is shaped to follow the outline of the torso itself.

6. A method as claimed in Claim 5, which includes incorporating an anatomically sculpted platform in the torso-supporting plinth.

7. A method of manufacturing a surgical simulator substantially as hereinbefore described with reference to the accompanying drawings.

8. A surgical simulator made by the method claimed in any one of the preceding claims.

9. A method of training surgeons and/or radiologists which includes the use of a surgical simulator as claimed in Claim 8.

10. A method of training as claimed in Claim 9, which includes the use of a sensor system for monitoring the carrying out of the simulated surgical techniques.

11. A method of training as claimed in Claim 10, in which said sensor system comprises a digital camera movable along a track fixed to a plate removably mounted in the access opening of the abdominal cavity of the simulated torso.

12. A sensor system for monitoring the carrying out of simulated surgical techniques, said sensor system comprising a digital camera movable along a track fixed to a plate removably mounted in an access opening of an abdominal cavity of a simulated torso.

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Claims searched:	1-11	**Date of search:**	22 September 1999

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Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.Q): G5G(G4,G16)

Int Cl (Ed.6): G09B

Other: Online:WPI,EPODOC,JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	GB 2324902 A	(SIMUTECH) see page 4 line 1 et seq	1
A	WO 96/42076 A1	(SIMULAB) see page 7 line 23 et seq	1

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
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